510(k) Summary

A. 510(k) Summary of Safety and Effectiveness

Contact

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Irvine, CA 92618

Date

August 1, 2000

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device name

Classification:	Liquid chemical germicide
Trade Name:	CIDEX® OPA Solution
Proprietary Name:	0.55% *ortho*-phthalaldehyde Solution

Legally marketed device

CIDEX® OPA Solution, 510(k) number 991487, October 1999

CIDEX® OPA Solution, Special 510(k) number 001381, May 2000

Device description

CIDEX® OPA Solution is formulated to contain 0.55% w/v of *ortho*-phthalaldehyde. The resultant solution contains a corrosion inhibitor, chelating agents, and a dye in a phosphate buffer. *ortho*-Phthalaldehyde is chemically related to glutaraldehyde in that they are both aldehydes. The mechanism of action of *ortho*-phthalaldehyde is postulated to be similar to glutaraldehyde and is based on powerful binding of the aldehyde to the outer cell wall of the organism.

Intended use	CIDEX® OPA Solution is a high level disinfectant for reprocessing heat sensitive medical devices, for which sterilization is not suitable, and when used according to the Directions for Use. High level disinfectant: CIDEX® OPA Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the CIDEX® OPA Solution Test Strips, at 20°C (68°F) with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days. Minimum Effective Concentration (MEC): 0.3%
Efficacy Testing	CIDEX® OPA Solution was tested using the standard array of microbiology tests for germicidal efficacy. Tests demonstrated sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal efficacy of CIDEX® OPA Solution. The CIDEX® OPA Solution used within the test protocols represented end of shelf life, reuse stressed, and MEC concentration of 0.3% conditions. Sporicidal: CIDEX® OPA Solution is a sporicidal agent as defined by the AOAC Sporicidal Activity Test with an exposure time of at least 32 hours at 20°C. Simulated Use: The reused and diluted CIDEX® OPA Solution at an MEC of 0.3% concentration at 20°C is effective against *Mycobacterium terrae* in artificial soil. In Use Testing: One hundred endoscopes used for bronchoscopy, gastroscopy, and colonoscopy were studied to determine the efficiency of CIDEX® OPA Solution for high level disinfection. The results support the claim of high level disinfectant for CIDEX® OPA Solution.

Biocompatibility	CIDEX® OPA Solution was evaluated for biocompatibility. The active ingredient and the formulated product were subjected to a panel of toxicologic tests, including acute oral and dermal toxicity, skin sensitization, genetic toxicity, *in vitro* and *in vivo* systems, subchronic oral toxicity and developmental toxicity tests. All animal toxicity data indicate that the product is at least as safe for human use as the predicate device. Biocompatibility of product residues testing was conducted. Results indicate that CIDEX® OPA Solution residuals absorbed onto materials commonly used in reprocessed medical devices are at levels well below those, which cause toxic effects in animals.
Material compatibility	CIDEX® OPA Solution was evaluated for its effect on materials commonly used to fabricate medical devices, medical devices and dental devices. Multiple disinfection soaks over extended periods of time resulted in minimal effect on the test articles. The effects seen were similar to those seen with the predicate device.
Stability	CIDEX® OPA Solution was tested and found stable for 24 months at 15-30°C. CIDEX® OPA Solution was tested under "open bottle" conditions and found stable for 75 days at 15-30°C. The change to the device is the increase in open bottle shelf life from 30 days to 75 days.
Conclusion	The data presented and the equivalence demonstrated to the predicate device support the claim of substantial equivalency for CIDEX® OPA Solution. CIDEX® OPA Solution is safe and effective as a high level disinfectant when used as labeled for reprocessing heat sensitive medical devices. AOAC Sporicidal Test results showed sporicidal activity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2000

Mr. Neelu Medhekar
Project Manger
Advanced Streilization Products
Division of Ethicon, Incorporated
33 Technology Drive
Irvine, California 92618

Re: K002401
Trade Name: Cidex OPA Solution
Regulatory Class: II
Product Code: MED
Dated: August 4, 2000
Received: August 7, 2000

Dear Mr. Medhekar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002401

Indications for Use

ADVANCED STERILIZATION PRODUCTS®
a Johnson & Johnson company
REGULATORY AFFAIRS DEPARTMENT

Indications for Use

510(k) Number: To Be Assigned

Device Name CIDEX® OPA Solution

Indications For Use:

CIDEX® OPA Solution is a high level disinfectant for reprocessing ~~heat sensitive medical~~ devices, for which sterilization is not suitable, and when used according to the Directions for Use.

High Level Disinfectant: CIDEX® OPA Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by CIDEX® OPA Solution Test Strips, at 20° C (68° F) with an immersion time of at least 12 minutes for a reuse period not to exceed 14 days.

Minimum Effective Concentration (MEC): 0.3%.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002401